DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 5, 2014

BioMonde
Ms. Rosina Robinson, RN, MEd, RAC
Aptiv Solutions
62 Forest Street, Suite 300
Marlborough, Massachusetts 01752

Re: K142020
Trade/Device Name: BIOMONDE LARVAL DEBRIDEMENT THERAPY PRODUCTS, LARVAE 100/200/300 AND BIOBAG 50/100/200/300/400
Regulatory Class: Unclassified
Product Code: NQK
Dated: October 15, 2014
Received: October 16, 2014

Dear Ms. Robinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142020

Device Name
BIOMONDE LARVAL DEBRIDEMENT THERAPY PRODUCTS, LARVAE 100/200/300 AND BIOBAG 50/100/200/300/400

Indications for Use *(Describe)*
The BioMonde Larval Debridement Therapy Products - Larvae 100/200/300 are indicated for debridement of non-healing necrotic skin and soft tissue wounds, including pressure ulcers, venous stasis ulcers, neuropathic foot ulcers, and non-healing traumatic or post-surgical wounds.

The BioMonde Larval Debridement Therapy Products - BioBag 50/100/200/300/400 are indicated for debridement of non-healing necrotic skin and soft tissue wounds, including pressure ulcers, venous stasis ulcers, neuropathic foot ulcers, and non-healing traumatic or post-surgical wounds.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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5. 510(K) SUMMARY

BIOMONDE
LARVAL DEBRIDEMENT THERAPY PRODUCTS
LARVAE 100/200/300 AND BIOBAG 50/100/200/300/400
(*PER 21CFR 807.92*)

1. SUBMITTER/510(K) HOLDER

BioMonde (*a trading name of ZooBiotic Limited*)
Units 2-4 Dunraven Business Park
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United Kingdom

Contact Person: Suzanne Morgan
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Date Prepared: November 4, 2014

2. DEVICE NAME

Proprietary Name: Larval Debridement Therapy Products – Larvae 100/200/300 and BioBag 50/100/200/300/400
Common/Usual Name: Larval debridement therapy products
Classification Name: Unclassified

3. PREDICATE DEVICES

- BioMonde Larval Debridement Therapy Products – Larvae 100/200/300 (K123449)
- BioMonde BioBag 50/100/200/300/400 (K131221)

4. DEVICE DESCRIPTION

The BioMonde Larval Debridement Therapy Products – Larvae 100/200/300 and BioMonde BioBag 50/100/200/300/400 products are live larvae, stage I and II, of the green bottle fly *Lucilia sericata*, provided either loose or within a sterile bag, respectively. The larvae are derived from disinfected fly eggs. Larvae are transferred under controlled manufacturing conditions into sterilized transport tubes or sterilized bags which are then placed into sterile transport tubes. These tubes are additionally pouched and boxed for transport. Upon arrival at the treatment location, they are applied to the wound and covered with permeable and absorbent dressings (not provided).

The modification to these products consists of replacing the feed used for stock flies from liver to a special mixture of nutrients called the "Carnival Diet". The Carnival Diet is also used to rear new fly generations and as a medium to induce egg laying. The reason for changing to this feeding material is to reduce the risk of transmission of viruses by removing the use of unprocessed animal organs and change to using pharmaceutical-grade animal-derived material.

5. INDICATION FOR USE/INTENDED USE

The BioMonde Larval Debridement Therapy Products - Larvae 100/200/300 are indicated for debridement of non-healing necrotic skin and soft tissue wounds, including pressure ulcers, venous stasis ulcers, neuropathic foot ulcers, and non-healing traumatic or post-surgical wounds.

The BioMonde Larval Debridement Therapy Products - BioBag 50/100/200/300/400 are indicated for debridement of non-healing necrotic skin and soft tissue wounds, including pressure ulcers, venous stasis ulcers, neuropathic foot ulcers, and non-healing traumatic or post-surgical wounds.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE/S

The technological characteristics of the modified BioMonde Larval Debridement Therapy Products are unchanged from that of the cleared parent devices with the sole difference being that flies raised on the Carnival Diet do not lay their eggs on liver.

Side-by-Side Comparison of the Technological Characteristics of the Modified and Parent BioMonde Larval Debridement Therapy Products (Larvae 100/200/300 and BioBag 50/100/200/300/400)

Characteristic	Modified BioMonde Larval Debridement Therapy Products	Parent	
		LARVAE 100/200/300 K123449	BIOBAG 50/100/200/300/400 K131221
Fundamental Technological Characteristics			
Lucilia sericata/Phaenecia sericata from a closed, monitored colony	Yes	Yes	Yes
Oviposition takes place on liver obtained from an approved supplier of animal tissue. Eggs are carefully removed from the liver and weighed.	No	Yes	Yes
Collected eggs are separated using sodium sulfite solution and mechanical agitation prior to sieving to ensure only single eggs enter the disinfection process.	Yes	Yes	Yes
Eggs are disinfected in a two stage process using 7.2% formaldehyde solution and 3.9% peracetic acid solution, after which they are rinsed with sterile sodium chloride 0.9%.	Yes	Yes	Yes
Disinfected eggs are inoculated onto the surface of a defined growth medium (Lucilia agar) contained in 90mm petri dishes. The petri dishes are placed into an incubator for 20-24 hours at 31-35°C where the eggs hatch and the larvae reach 2-6mm in size.	Yes	Yes	Yes
Available in containers of varying numbers of larvae	Yes	Yes	Yes
Larvae are removed from the growth medium using a loop or spoon and placed into containers marked with fill heights for the dosage required.	Yes	Yes	Yes
The correct dosage of larvae is transferred to a sterile transport tube.	Same as parent devices	Yes	No
The transport tubes containing the larvae are labeled, the tube is placed into a pouch which is labeled and the pouch is placed into a labeled transport box with the instructions for use.	Yes	Yes	Yes

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

This Premarket Notification presents bench testing that demonstrates that the product, as modified by changing the feed of the stock flies from liver to the special mixture of nutrients called the "Carnival Diet" fulfills the same design and performance specifications disclosed in the cleared 510(k)s for the BioMonde Larvae 100/300/300 and BioBag 50/100/200/300/400.

Non-clinical testing of stock flies and larvae was performed to demonstrate the substantial equivalence of design and performance of flies and larvae reared with liver (predicate control) and flies and larvae reared with the Carnival Diet (proposed modified product). Testing consisted of the following:

1. Monitoring of the 4 descriptive parameters for fly colony health & fitness (larval duration, pupae weight, pupae hatch success and egg yield); and
2. Performance of the Larval Activity Assay (consumption of protein by a set number of the larvae over a 2-day period in a defined apparatus) and enzyme pattern of larval secretions.

The results obtained using the Carnival Diet for five (5) generations were compared with those observed with flies and larvae fed with liver (control). The comparative testing demonstrates that the flies and larvae reared with Carnival Diet appear to be slightly smaller in size but are as healthy and effective in terms of debridement activity as those derived from flies reared on liver. No difference in enzyme patterns was found between the control and the Carnival Diet groups. Testing across generations indicates that adaptation to the Carnival Diet over at least 3 generations is necessary to assure satisfactory performance.

When the proposed product is compared to flies and larvae of the two predicate devices, the proposed product is substantially equivalent in performance.

8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

No clinical data were included in this Traditional 510(k) Premarket Notification.

9. SUMMARY OF OTHER INFORMATION

Other information provided in this Traditional 510(k) Premarket Notification includes manufacturing information which is fundamentally unchanged from that of the cleared devices.

10. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

Based on the information provided in this Traditional 510(k) Premarket Notification, BioMonde has determined that the products as modified are substantially equivalent, that differences are minor, and do not raise new safety and effectiveness questions.